

HOUSE BILL 435

C3

9lr1092
CF SB 405

By: **Delegates Kelly, Bagnall, Bromwell, Hill, Metzgar, Morgan, Saab, Valentino-Smith, and K. Young**

Introduced and read first time: January 31, 2019

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Prescription Drugs – Formulary Changes**

3 FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and health
4 maintenance organizations from making certain formulary changes during certain
5 time periods, except under certain circumstances; defining a certain term; providing
6 for the application of this Act; and generally relating to formulary changes for
7 prescription drugs.

8 BY repealing and reenacting, with amendments,

9 Article – Insurance

10 Section 15–831

11 Annotated Code of Maryland

12 (2017 Replacement Volume and 2018 Supplement)

13 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

14 That the Laws of Maryland read as follows:

15 **Article – Insurance**

16 15–831.

17 (a) (1) In this section the following words have the meanings indicated.

18 (2) “Authorized prescriber” has the meaning stated in § 12–101 of the
19 Health Occupations Article.

20 (3) “Formulary” means a list of prescription drugs or devices that are
21 covered by an entity subject to this section.

22 (4) (i) “Member” means an individual entitled to health care benefits

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 for prescription drugs or devices under a policy issued or delivered in the State by an entity
2 subject to this section.

3 (ii) “Member” includes a subscriber.

4 **(5) (I) “UTILIZATION MANAGEMENT RESTRICTION” MEANS A**
5 **RESTRICTION ON COVERAGE FOR A PRESCRIPTION DRUG ON A FORMULARY.**

6 **(II) “UTILIZATION MANAGEMENT RESTRICTION” INCLUDES:**

7 **1. IMPOSING OR ALTERING A QUANTITY LIMIT FOR A**
8 **PRESCRIPTION DRUG;**

9 **2. ADDING A REQUIREMENT THAT AN ENROLLEE**
10 **RECEIVE A PRIOR AUTHORIZATION FOR A PRESCRIPTION DRUG; AND**

11 **3. IMPOSING A STEP THERAPY PROTOCOL RESTRICTION**
12 **FOR A PRESCRIPTION DRUG.**

13 (b) (1) This section applies to:

14 (i) insurers and nonprofit health service plans that provide coverage
15 for prescription drugs and devices under individual, group, or blanket health insurance
16 policies or contracts that are issued or delivered in the State; and

17 (ii) health maintenance organizations that provide coverage for
18 prescription drugs and devices under individual or group contracts that are issued or
19 delivered in the State.

20 (2) An insurer, nonprofit health service plan, or health maintenance
21 organization that provides coverage for prescription drugs and devices through a pharmacy
22 benefit manager is subject to the requirements of this section.

23 (3) This section does not apply to a managed care organization as defined
24 in § 15–101 of the Health – General Article.

25 **(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION,**
26 **DURING A PLAN YEAR AND THE OPEN ENROLLMENT PERIOD THAT PRECEDES THE**
27 **PLAN YEAR, AN ENTITY SUBJECT TO THIS SECTION MAY NOT:**

28 **(I) REMOVE A PRESCRIPTION DRUG FROM A FORMULARY;**

29 **(II) IF A GENERIC EQUIVALENT IS NOT AVAILABLE AND THE**
30 **FORMULARY INCLUDES TWO OR MORE BENEFIT TIERS THAT ESTABLISH DIFFERENT**
31 **DEDUCTIBLE, COPAYMENT, OR COINSURANCE REQUIREMENTS FOR PRESCRIPTION**

1 DRUGS IN EACH BENEFIT TIER, MOVE A PRESCRIPTION DRUG TO A BENEFIT TIER
2 THAT REQUIRES A MEMBER TO PAY A HIGHER DEDUCTIBLE, COPAYMENT, OR
3 COINSURANCE AMOUNT FOR THE PRESCRIPTION DRUG; OR

4 (III) ADD A UTILIZATION MANAGEMENT RESTRICTION TO A
5 PRESCRIPTION DRUG IN THE FORMULARY.

6 (2) AN ENTITY SUBJECT TO THIS SECTION MAY REMOVE A
7 PRESCRIPTION DRUG FROM A FORMULARY OR IMPOSE A UTILIZATION
8 MANAGEMENT RESTRICTION IF AT ANY TIME:

9 (I) THE U.S. FOOD AND DRUG ADMINISTRATION ISSUES A
10 NOTICE, GUIDANCE, WARNING, ANNOUNCEMENT, OR ANY OTHER STATEMENT ABOUT
11 THE PRESCRIPTION DRUG THAT CALLS INTO QUESTION THE CLINICAL SAFETY OF
12 THE PRESCRIPTION DRUG;

13 (II) THE MANUFACTURER OF THE PRESCRIPTION DRUG HAS
14 NOTIFIED THE U.S. FOOD AND DRUG ADMINISTRATION OF A POTENTIAL OR
15 PERMANENT DISCONTINUANCE OR AN INTERRUPTION IN MANUFACTURING OF THE
16 PRESCRIPTION DRUG; OR

17 (III) THE PRESCRIPTION DRUG IS APPROVED BY THE U.S. FOOD
18 AND DRUG ADMINISTRATION FOR USE WITHOUT A PRESCRIPTION.

19 (3) THIS SUBSECTION DOES NOT PROHIBIT AN ENTITY SUBJECT TO
20 THIS SECTION FROM:

21 (I) ADDING A PRESCRIPTION DRUG TO A FORMULARY AT ANY
22 TIME; OR

23 (II) MODIFYING A FORMULARY AT THE TIME OF RENEWAL AND
24 BEFORE THE OPEN ENROLLMENT PERIOD IF, NO LATER THAN 60 DAYS BEFORE THE
25 MODIFICATION IS EFFECTIVE, THE ENTITY:

26 1. PROVIDES WRITTEN NOTICE OF THE MODIFICATION
27 TO THE AFFECTED MEMBER AND THE AFFECTED MEMBER'S AUTHORIZED
28 PRESCRIBER; AND

29 2. POSTS THE MODIFICATION ON THE ENTITY'S ONLINE
30 FORMULARY.

31 [(c)] (D) Each entity subject to this section that limits its coverage of
32 prescription drugs or devices to those in a formulary shall establish and implement a
33 procedure by which a member may receive a prescription drug or device that is not in the

1 entity's formulary in accordance with this section.

2 **[(d)] (E)** The procedure shall provide for coverage for a prescription drug or
3 device that is not in the formulary if, in the judgment of the authorized prescriber:

4 (1) there is no equivalent prescription drug or device in the entity's
5 formulary;

6 (2) an equivalent prescription drug or device in the entity's formulary:

7 (i) has been ineffective in treating the disease or condition of the
8 member; or

9 (ii) has caused or is likely to cause an adverse reaction or other harm
10 to the member; or

11 (3) for a contraceptive prescription drug or device, the prescription drug or
12 device that is not on the formulary is medically necessary for the member to adhere to the
13 appropriate use of the prescription drug or device.

14 **[(e)] (F)** A decision by an entity subject to this section not to provide access to or
15 coverage of a prescription drug or device in accordance with this section constitutes an
16 adverse decision as defined under Subtitle 10A of this title if the decision is based on a
17 finding that the proposed drug or device is not medically necessary, appropriate, or
18 efficient.

19 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all
20 policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or
21 after January 1, 2020.

22 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
23 October 1, 2019.